WS7.5 Prolonged improvement in lung function and quality of life in cystic fibrosis: a 24-week extension study of levofloxacin nebulization solution (APT-1026) versus tobramycin nebulization solution in stable CF patients with chronic *Pseudomonas aeruginosa* infection

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Objectives: A new inhaled antimicrobial (levofloxacin nebulizer solution; APT-1026) was studied prospectively to assess its utility in managing patients with chronic *Pseudomonas aeruginosa* (PA) lung infection.
Methods: This was a non-randomized, single-arm 24-wk Extension to a randomized, open-label Phase 3 study (MPEX-209) comparing APT-1026 (240 mg BID) with tobramycin nebulization solution (TNS; 300 mg BID) over three 28-day on/28-day off cycles in CF patients with chronic PA lung infection. Patients either continued cyclic treatment with APT-1026 or switched from TNS to APT-1026 following prior cyclic TNS for 3 additional cycles. Efficacy endpoints included spirometry and CFQ-R respiratory domain; safety was assessed at 28-day intervals.
Results: 88 patients enrolled in the Extension to receive APT-1026 for three additional cycles (56 continuing APT-1026; 32 switched from TNS). In 47 patients completing 6 cycles of APT-1026, FEV_1 % predicted increased similarly in Cycles 1–3 of MPEX-209 and Cycles 4–5 of the Extension, with lesser response at Cycle 6. Most (72 to 79%) patients switched from TNS to APT-1026 improved FEV_1 above their post-TNS baselines during Cycles 4–6. Patients switched from TNS to APT-1026 also experienced symptomatic benefit assessed by CFQ-R during the Extension, resembling patients originally receiving APT-1026. APT-1026 was well-tolerated and no new significant AEs were identified during the Extension. Adverse events led to early Extension discontinuation in 4 patients.
Conclusion: This Extension study contributes to evidence that APT-1026 240 mg BID is safe and effective for long-term management of chronic lung infection due to PA.

WS7.6 Incorporation of a third inhaled antipseudomonal antibiotic class into the management of patients at an adult CF care center

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Objectives: To evaluate how inhaled antibiotic (iABX) management of patients (pts) seen at The Cleveland Adult CF Center was affected by introduction of aztreonam for inhalation solution (Az).
Methods: Treatment records for pts receiving inhaled colistin (Co), an inhaled aminoglycoside (Ag), or Az at $\geqslant$1 encounter from 2009–2012 were obtained from the local Port CF Patient Registry. Annual iABX use and regimens (month on/month off, continuous, or other) were compared.
Results: 172 pts were studied; 127 in 2009, 118 in 2010, and 130 in 2011 and 2012. From 2009–2012, the prevalence of Co and Ag use at any encounter (independent of regimen) decreased (56% to 41% and 74% to 62%, respectively) while Az prevalence increased from 3% to 50%. Overall prevalence of month-on/month-off or continuous iABX use did not change over the period. However, the prevalence of patients alternating iABX (Co/Ag, Co/Az, or Az/Ag) increased from 20% in 2009 to 39% in 2012. The prevalence of patients that used $\geqslant$2 classes of iABX at any point in the year (not necessarily in alternating regimens) increased from 28% in 2009 to 45% in 2012.
Conclusion: At the Cleveland Adult CF Center, introduction of Az in 2010 did not coincide with a change in the prevalence of patients using month on/month off or continuous iABX regimens, although the prevalence of individual iABX class use did change. In contrast, Az introduction did lead to a substantial increase in the prevalence of patients reported to be receiving multiple iABX classes during the year. The increasing prevalence of multiple iABX use has important implications for the design of future iABX studies, patient care, and evaluation of treatment burden.